International Conference on Harmonization (ICH)
M2 EWG Meeting - Summary
London, 05 February - 08 February 2001

Participants:
EU: Stan van Belkum, Karel de Neef, Miguel Bley, M. T. Carrasco Benitez, Tim Buxton
EFPIA: Gabriele Disselhoff, Andrew Marr, Stephan Laage
FDA: Greg Brolund (Rapporteur), Melissa Chapman, Bill Ridgely
PhRMA: Kris Arora, Bob Hizer
MHLW: Mihoko Okada
JPMA: Tohru Uwoi, Tetsuro Shimokariya, Hitoshi Asano, Harv Martens, Keiji Sawamukai, Masatochi Ozeki, Tadao Akiyama
Observer: Bob Kapitany, Gerald Kukko

Topics discussed at this meeting included:

- concepts for the technical approach to be used in the development of the eCTD DTD,
- submission and individual document tracking and lifecycle requirements,
- development and prototyping of at least one eCTD instance using DTD version 2.5 as the basis for continued development,
- relationship of the CTD to the eCTD in terms of numbering, granularity, etc.

The DTD provides a detailed structure for CTD modules 2 through 5 and lifecycle support for all modules. FDA, EU, MHLW and TPP will each develop guidance and necessary DTD's which define the submission of regional information in all modules (1,2,3,4,5).

FDA and TPP confirmed that the eCTD DTD model is intended to provide the ability to transport the future electronic IND submission.

Documents distributed:

- 1 page summary
- Version 2.5 of the eCTD DTD

The next meeting is in Tokyo, Japan May 21-24, 2001.